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R&D Inc. and Norton (Waterford) Ltd.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TEVA BRANDED PHARMACEUTICAL	:	Consolidated Civ. Action No.
	:	20-10172 (JXN) (MAH)
PRODUCTS R&D, INC., and	:	
NORTON (WATERFORD) LTD.,	:	
	:	
Plaintiffs,	:	HIGHLY CONFIDENTIAL –
	:	FILED UNDER SEAL
v.	:	
	:	
CIPLA LTD.,	:	
	:	
Defendant.	:	
	:	

CORRECTED PLAINTIFFS TEVA BRANDED PHARMACEUTICAL PRODUCTS R&D, INC. AND NORTON (WATERFORD) LTD.'S OPENING POSTRIAL BRIEF ADDRESSING INFRINGEMENT, OBJECTIVE INDICIA, AND ADMISSIBILITY

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I. Introduction

Cipla's ANDA Products infringe Teva's patent claims. Cipla's non-infringement arguments hinged on claim constructions the Court's *Markman* decision rejected squarely, leaving Cipla with two options: (1) admit infringement or (2) dispute infringement by denying facts plainly visible to everyone in the Courtroom. Although Teva could have carried its burden as to multiple patents by simply asking the Court to look at the Cipla's device and observe what is plain as day, Teva nevertheless presented a mountain of evidence proving conclusively that Cipla's device infringes all three Asserted Patents: U.S. Patent Nos. 9,463,289; 9,808,587; and 10,561,808. Teva's expert, Dr. David Lewis, supported his infringement opinion with common sense, detailed explanations of Cipla's products, and experimental results. In contrast, Cipla's expert, Mr. Gregor Anderson, offered nothing more than conclusory testimony without a shred of supportive evidence or data, often in direct contradiction to his prior sworn testimony. He also conducted no experiments whatsoever.

Lacking any evidence of noninfringement, Cipla resorted to arguing a distinction between tapes and gears that is irrelevant as a matter of law (since the asserted claims recite neither tape nor gears), redrafting the claims to include additional requirements that do not exist, and asking the Court to shut its eyes, literally, to the facts. In short, Cipla did not offer any ***evidence*** to support its noninfringement theories, which were advanced solely via attorney argument in opening statement or objection. The preponderance of evidence weighs heavily in Teva's favor on the question, and the

Court should find that Cipla's device infringes the Asserted Claims.

II. Cipla Infringes Each Asserted Patent.

Infringement requires a showing that the accused product "more likely than not" satisfies the disputed limitation. *Warner-Lambert Co. v. Teva Pharms. USA, Inc.*, 418 F.3d 1326, 1341 & n.15 (Fed. Cir. 2005); *see also Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 845 F.3d 1357, 1364 (Fed. Cir. 2017) (proof of infringement requires "preponderance of the evidence"). Teva has far exceeded this demand.

A. Cipla Infringes the '289 Patent.

Cipla's ANDA Products infringe the asserted claims of the '289 Patent. There is no credible evidence to the contrary. Indeed, the Court's *Markman* order foreclosed every (flawed) non-infringement theory Cipla disclosed over the course of the case. At trial, Cipla thus appropriately conceded its products satisfy the vast majority of the limitations of the Asserted Claims. But instead of accepting the consequences of the *Markman* order, Cipla chose to present a new, undisclosed, and unsupported non-infringement theory at trial—namely, that a particular "rib" in its inhaler body is not an "inner wall canister support formation" (even though the other ribs in its device are) because *that* rib purportedly is not "arranged to reduce canister rocking."

This belated theory fails, and the weight of the evidence—not to mention common sense—is firmly on Teva's side. Teva's expert Dr. Lewis testified and demonstrated unequivocally that the disputed rib is a an "inner wall canister support formation." Dr. Lewis supported his opinion with common sense, a detailed analysis

of Cipla's accused products, and confirmatory experiments. By contrast, Cipla's expert Mr. Anderson offered only a few lines of conclusory testimony based on the wrong claim construction, Tr. 479:14-21, and provided no data or analysis of his own, *id.* at 519:8-521:8. This is hardly surprising—until he took the stand, Mr. Anderson had *agreed* that the exact rib in question was an "inner wall canister support formation." He testified to that fact four times at deposition, as Teva demonstrated on cross examination. FOF 79-83; Ex A-D.[1] Mr. Anderson's conclusory and contradictory testimony at trial defies the record evidence and cannot avert a finding of infringement.

1. Cipla's ANDA Products Satisfy Each Undisputed Limitation of the Asserted Claims of the '289 Patent.

At trial, Teva adduced evidence that Cipla's ANDA Products infringe claims 1, 2, 4, 6, and 7 ("the Asserted Claims"). Cipla contested infringement of only a single term in a single limitation of claim 1, underlined below, and did not dispute that its products satisfied every other limitation of every Asserted Claim. FOF 4; Tr. 503:23-504:4 (claim 1), FOF 90-105, Tr. 481:23-482:8 (dependent claims); *see also* 523:3-8, 525:3-527:11. The unrebutted evidence of infringement for each claim and undisputed limitation is shown in chart form below.[2] Section II.A.2 *infra* addresses the single disputed issue.

[1] Exhibits to the Declaration of Liza M. Walsh. The deposition transcript excerpts at Ex. A-D were submitted at D.E. 247-248 and reattached for the Court's convenience.

[2] All stipulated facts were admitted into evidence at trial. Tr. 425:10-426:9.

a. Claim 1

Claim Language (JTX-003)	Unrebutted Evidence of Infringement
1. An inhaler for metered dose inhalation, the inhaler comprising:	Findings of Fact ("FOF") 5-6; Tr. 192:6-21 (Lewis); D.E. 210, at 9 (Undisputed Fact No. 3); PTX-411; *see* PDX-2-033.
a main body having a canister housing	FOF 7-11; Tr. 192:23-193:16 (Lewis); D.E. 210, at 9 (Undisputed Fact No. 4); PTX-411; *see* PDX-2-034.
a medicament canister, which is moveable relative to the canister housing and	FOF 12-14; Tr. 193:17-194:20 (Lewis); D.E. 210, at 9 (Undisputed Fact Nos. 5-6); PTX-411; *see* PDX-2-035.
arranged to mate with a canister fire stem of the medicament canister, and	FOF 15-16; Tr. 194:22-195:21 (Lewis); D.E. 210, at 9 (Stipulated Fact No. 7); PTX-411; *see* PDX-2-036.
a dose counter	FOF 17-18; Tr. 195:23-197:3 (Lewis); D.E. 210, at 10 (Undisputed Fact No. 8); PTX-372; PTX-411; *see* PDX-2-037.
having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister	FOF 19-25; Tr. 197:5-204:6 (Lewis); PTX-180; PTX-181; PTX-372; PTX-411; *see* PDX-2-038; PDX-2-049; PDX-2-050.
wherein the canister housing has an inner wall	FOF 26-27; Tr. 204:7-205:1 (Lewis); D.E. 210, at 10 (Undisputed Fact No. 9); PTX-411; *see* PDX-2-039.
and a first inner wall canister support formation extending inwardly from a main surface of the inner wall, and	FOF 28-35; Tr. 205:4-207:4 (Lewis); PTX-411; PTX-373; *see* PDX-2-040.
wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port,	FOF 36-38; Tr. 207:5-208:5 (Lewis); PTX-411; PTX-373; D.E. 210, at 10 (Undisputed Fact No. 11); *see* PDX-2-041.
the inner wall canister support formation, the actuation member, and the central outlet port lying in a common plane coincident with the longitudinal axis X ("the Common Plane Limitation").	Cipla does not dispute that the "rib" located between the two mounting tabs lies in a common plane with the actuation member, the central outlet port, and that this plane is coincident with the longitudinal axis X. FOF 39-43; PTX-372; PTX-411; Tr. at 175:16-176:8; 208:5-210:1, 211:16-18, 502:23-504:4; *see* PDX-

	2-026; PDX-2-042. As described below, Cipla disputes only whether that rib is an "inner wall canister support formation."

b. Claim 2

Claim Language (JTX-003)	Unrebutted Evidence of Infringement
2. The inhaler as claimed in claim **1**,	See citations above for claim 1.
wherein the medicament canister is moveable relative to the dose counter.	FOF 90-91; Tr. 257:15-260:17 (Lewis); D.E. 206, at 10 (Undisputed Fact No. 12); PTX-372; PTX-411; *see* PDX-2-072.

c. Claim 4

Claim Language (JTX-003)	Unrebutted Evidence of Infringement
4. The inhaler as claimed in claim **1**,	See citations above for claim 1.
wherein the first inner wall canister support formation comprises a support rail which extends longitudinally along an inside surface of the main body.	FOF 94-98; Tr. 260:18-261:5 (Dr. Lewis); PTX-372; PTX-411; *see* PDX-2-073.

d. Claim 6

Claim Language (JTX-003)	Unrebutted Evidence of Infringement
6. The inhaler as claimed in claim **4**	See citations above for claims 1 and 4.
further comprising a plurality of support rails each of which extends longitudinally along an inside surface of the main body.	FOF 99-101; Tr. 261:6-262:7 (Lewis); D.E. 206, at 10 (Undisputed Fact No. 10) (plurality of "ribs"); PTX-372; PTX-411; *see* PDX-2-074.

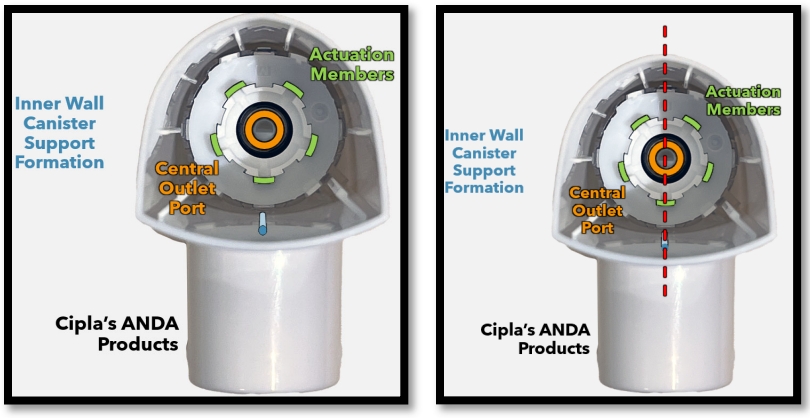
e. Claim 7

Claim Language (JTX-003)	Unrebutted Evidence of Infringement
7. The inhaler as claimed in claim **6**	See citations above for claims 1, 4, and 6.
wherein two of the plurality of support rails are positioned at	FOF 102-104; Tr. 262:8-24 (Lewis); PTX-372; PTX-411; *see* PDX-2-075.

opposite ends of the inside surface of the main body to face each other.	

2. The "Front Rib" Is an "Inner Wall Canister Support Formation."

At trial, Cipla disputed only a single limitation of the asserted claims: Cipla concedes that its ANDA Products contain a "rib" that lies in a common plane with an actuation member and the center of the central outlet port, but nevertheless asserts that the "rib" is not an "inner wall canister support formation." FOF 42-43. In other words, Cipla concedes that there is a "rib" in its ANDA Products that satisfies every requirement of the final limitation of claim 1 (which the parties have called the "Common Plane Limitation"), *if* that rib is an "inner wall canister support formation." *Id.* Consistent with the Court's *Markman* opinion, there is no dispute that the rib (shown below in blue and referred to as the "front" rib or the "6 o'clock rib") located between the two "mounting tabs" is "aligned in a single plane such that a straight line [red] can be drawn through the center of the central outlet port [orange], the [rib] [blue], and the actuation member [green]." D.E. 218, at 2 (Markman Order).



See PDX-2-026 (pre- and post-animation); Tr. 503:23-504:4 (Anderson); FOF 41.

The sole dispute arises because Cipla, for the very first time at trial, asserted that the (blue) rib in question is ***not*** an "inner wall canister support formation." Cipla's belated theory is desperation, not evidence, and it is plainly incorrect.

a. The Front Rib Is Visibly a "Formation Arranged to Reduce Canister Rocking."

As Dr. Lewis testified, the "front" rib in Cipla's device is an inner wall canister support formation because it meets the parties' agreed-upon definition of that term—"a formation arranged to reduce canister rocking." D.E. 102, at 4; FOF 45. That the rib reduces rocking is plain from the rib's very existence—as Dr. Lewis explained, "you can tell by simply looking." Tr. 213:12-16; FOF 46-49. The rib visibly extends inwardly into the inhaler body, and thereby "necessarily limits the canister's freedom of movement in the direction of the front of the device." FOF 47 (quoting Tr. 206:20-207:4, 370:25-371:8 (Lewis)). No more is needed to appreciate that the front rib in question is "arranged to reduce canister rocking." FOF 49 (Tr. 222:9-12). That proposition is confirmed easily by holding the inhaler by the mouthpiece, pushing the canister forward, and observing that the canister contacts the rib in question and thereby stops its motion—just as Dr. Lewis testified and demonstrated, without refutation, multiple times, FOF 46-48:

- "When you hold the inhaler, you can just push it [the canister] and you can see it touches [the rib] before it touches the inner wall." Tr. 213:12-16 (Lewis).
- "[H]old the mouthpiece so you are not interfering with the body. And then

simply just push the canister, just tap it down. Then you can see it touches the middle [*i.e.*, disputed] rail and there is also gap. Meaning if you took that rail out, it would continue to move." *Id.* at 217:23-218:4, 218:14-219:5.

- "[A]s I touch it, [the canister] meets the rail. And I can also see there is a gap still there between the canister and the housing." Tr. 218:23-219:4.
- "I can see the rail supporting the canister." *Id.* at 221:25-222:8.
- "If you are holding the inhaler by the mouthpiece and then you push, it's going to hit the rib." Tr. 375:24-376:7.
- "I see the canister touching the front rib and I see a gap at the top, as well, of the inhaler body. So I see a touching of the canister to that rib." Tr. 400:11-22 (explaining "gap between canister and inhaler body . . . mean[s] that the canister is not touching the inhaler body.").

b. Dr. Lewis's Experiments Confirm that the Front Rib is a "Formation Arranged to Reduce Canister Rocking."

Cipla's only infringement defense rests on rebutting the self-evident conclusion that the front rib in its product is "arranged to reduce canister rocking." There is no evidence in the record to support Cipla's claim. *Supra* Section II.A.2.c. Instead, Cipla rests its case on unsupported attorney argument urging that proof of infringement in this case requires complicated experiments. *See* Tr. 216:5-12. This is simply untrue. *Supra* Section II.A.2.a. Nevertheless, Dr. Lewis ***did*** perform experiments that confirm his opinion the front rib is "arranged to reduce canister rocking." Cipla offered no evidence, let alone any experiments, in response.

1) Cipla's Canister Rocks More in the Absence of the Ribs.

Dr. Lewis testified that he compared the amount of canister rocking that can

occur in Cipla's device "as supplied"—that is, with all ribs and mounting tabs present—with a version of Cipla's device in which he removed all the ribs (but not the mounting tabs). Tr. 223:12-224:1; FOF 51-53. Unsurprisingly, Dr. Lewis concluded that in the absence of the ribs, Cipla's canister can rock more than it can when the ribs are present. Tr. 224:2-226:6; FOF 51. In particular, Dr. Lewis testified that removal of the ribs results in more than a millimeter of additional "front to back" rocking (*i.e.*, rocking towards or away from the front rib) even though the mounting tabs remained in the device—an amount of additional rocking that is "highly significant" in the context of dose counter accuracy. Tr. 224:2-226:6; FOF 52. As this test demonstrates, the ribs in Cipla's device are "arranged to reduce rocking."

Dr. Lewis performed this experiment as part of his infringement analysis establishing that Cipla's device contained an "inner wall canister support formation," long before Cipla revealed at trial its intention to argue that while some ribs in its device are inner wall canister support formations, according to Cipla, the rib it concedes lies in the common plane is not an inner wall canister support formation. As Dr. Lewis testified, the extra rocking he observed in the experiment, therefore, is attributable to removal of "both" the "front" rib and the ribs in the rear of the inhaler. FOF 53; Tr. 226:7-17. He also testified, on both direct and cross examination, that removal of the "front" rib is responsible for ***at least some*** of this movement, Tr. 226:13-17, 226:18-25, 378:12-379:8 ("[t]here is a contribution from both sides" even if test does not resolve numeric contribution from each), a fact that follows from Dr. Lewis's testimony

that the front rib extends inwardly into the inhaler body and thereby restricts the freedom of movement of the canister, and the observation that the rib visibly contacts the canister when the canister is rocked forward, Tr. 226:13-25; *supra* Section II.A.2.a.[3]

2) Removal of the Front Rib Causes Canister Rocking that Causes Dose Counter Errors

In addition to measuring rocking, Dr. Lewis performed further testing isolating the role of the front rib. These results confirm the front rib's effect on canister rocking and, in turn, dose counter accuracy. Tr. 229:4-10; FOF 54-72. Dr. Lewis recorded this testing in a video, PTX-178. Tr. 229:11-12. As visible in the video, Dr. Lewis altered Cipla's device by removing all the ribs, but not the mounting tabs. FOF 54. Then, as the video showed, Dr. Lewis rocked the canister "[t]owards the front of the inhaler, which is where the rib that we have been discussing has been removed." *Id.*; Tr. 230:1-

[3] Cipla objected to a portion of Dr. Lewis's testimony at 226:18-25, and moved to strike related testimony on cross examination at a portion of lines 379:16-20. Cipla argued that Dr. Lewis's statements connecting his measurements of front-to-back rocking to his observation that the front rail contributed to the rocking were unsupported by his reports. *See, e.g.*, Tr. 379:16-380:19. In particular, Cipla argued that Dr. Lewis's statement in his reports that "because the rib goes on to the inside, it necessarily restricts movement" "wasn't in any way in connection with Dr. Lewis's testing." Tr. 380:10-13. Cipla is wrong. The testing in question, as depicted in PDX-2-063, was first produced and described in Paragraph 181 and Exhibit B of Dr. Lewis's ***Opening*** Report. Ex. F. In his Reply Report, Dr. Lewis further connected that testing explicitly to the front rail, using precisely the language Cipla disputes. Ex. E ¶ 66. There, Dr. Lewis stated that the front rib "necessarily restricts the canister's movement in the direction of that rail," citing the same testing at Paragraphs 181 of his opening report, and explaining that that "[t]he measurements I reported in my Opening Report confirm this fact empirically." *Id.; see also* Ex. E ¶ 61. Cipla's objection is baseless. Regardless, the remainder of Dr. Lewis's testimony is more than sufficient to support his conclusions.

6; PTX-178. Dr. Lewis ***never*** rocked the canister backwards, so the removal of the rear ribs had no impact on the experiment—only the effect of the front rib at issue in Cipla's infringement argument was tested in this experiment. FOF 55 (Tr. 230:7-12; 247:24-248:4); PTX-178. Dr. Lewis then slid the canister down the front wall of the inhaler (against the wall where the "front" rib in question would have been located, had it not been removed). FOF 54; PTX-178. This fact ***alone*** demonstrates that the rib in question reduces canister rocking, since in the ribs absence the canister can contact the inhaler wall. FOF 56; Tr. 385:20-386:8 ("I am talking about sliding down the front face of that wall. If the formation is there, it will touch it, it will restrict movement."); *see also* 249:25-250:2; 403:17-404:7, 404:19-21.

Dr. Lewis's testing also shows that in the absence of the front rib, increased canister rocking toward the front of the inhaler in the direction of the (absent) front rib causes "count-not-fire" errors. FOF 57-58; PTX-178 (depicting eight increments of the counter without accompanying medication spray). Certainly, the construction of "inner wall canister support formation" does not require reduction or prevention of count-not-fire errors. FOF 59; D.E. 102 at 4-5. Nevertheless, the fact that—when the front rib is removed—the canister can rock so far towards the front of the inhaler that counting errors can occur supports Dr. Lewis's conclusion that the front rib is "arranged to reduce rocking." FOF 60-61. Teva's invention (an inner wall canister support formation in a common plane with the actuation member and central outlet port) was designed to reduce precisely this kind of rocking, and exactly these kinds of

dose counter inaccuracies. FOF 62; Tr. 169:16-171:13 172:9-173:2.

Cipla offered no evidence to rebut Dr. Lewis's experiments, and its expert performed no experiments to generate contrary conclusions.[4] FOF 63. Instead, Cipla took unsupported jabs at Dr. Lewis's work. For example, Cipla argued that "rocking while pushing" is not "rocking," Tr. 357:17-361:12, that its device is biased towards overcounting, Tr. 494:11-495:11, and also questioned Dr. Lewis about his alleged failure to follow patient instructions to "prime" the device twice before using it in the videoed experiment, Tr. 389:4-391:2 (citing PTX-093). None of these arguments undercut Dr. Lewis's experiment, offered as ***additional***—and perhaps excessive—evidence of the fact that the front rib is arranged to reduce canister rocking. ***First,*** nothing in the parties' agreed-upon construction of a "formation arranged to reduce canister rocking"—limits the timing of the rocking. FOF 64-65; D.E. 102, at 4; Tr. 405:14-406:10. Rocking ***while*** depressing the canister is still is rocking, as is rocking ***after*** pressing or ***before*** pressing, *id.*—patients rock the canister in all these ways, Tr. 272:19-24; 357:17-359:25; 404:22-405:1. ***Second,*** whether or not Cipla's device is biased toward overcounting, Dr. Lewis showed that removal of the front rib leads to overcounting errors. FOF 66. ***Third,*** there is nothing magical about a "priming" shot of an inhaler—priming is simply firing the inhaler into the air, rather than into a patient's mouth. PTX-

[4] While Mr. Anderson claimed to have conducted unspecified and undocumented experiments, he did not present them or the devices used in them, because Dr. Anderson destroyed those devices before trial. Tr. 520:21-521:8.

093 at 2; FOF 67. Cipla offered no evidence that had a "priming" ritual been performed in the video, the experimental results would have been different. FOF 68. Nor does anything suggest as much—Dr. Lewis's video recorded eight "fire-not-count" errors, and it is undisputed that the dose counter should not have counted those compressions regardless of whether it had been primed. FOF 58, 71; PTX-178. Those errors are the consequence of removing the front rib that Cipla doggedly insists (without evidence) serves no role whatsoever in reducing rocking, and they are exactly the errors Teva's invention was designed to prevent. FOF 72.

In sum, Dr. Lewis's experiments confirm that the front rib is "arranged to reduce canister rocking." The Court need not resolve every one of Cipla's whack-a-mole complaints in order to find infringement—Dr. Lewis's testimony, bolstered by his experiments, clearly establishes that it is "more likely than not" that the front rib is "arranged to reduce canister rocking." No more is required.

c. Cipla Adduced No Evidence for the Court to Weigh Against Dr. Lewis's Opinion.

Teva proved infringement by a preponderance of the evidence at trial. Cipla neither refuted Teva's evidence nor delivered on promises made during its opening statement that it would prove contrary facts. Instead, Cipla offered conclusory expert testimony using the wrong claim construction (and thus legally irrelevant) and in direct contradiction to the expert's repeated sworn deposition testimony. The evidence shows that it is far "more likely than not" that the front rib is "arranged to reduce canister

rocking," and thus that Cipla infringes. *Warner-Lambert Co.*, 418 F.3d at 1341-42 & n.15.

1) Mr. Anderson Offered Conclusory Testimony Using the Wrong Claim Construction.

Cipla's expert, Mr. Anderson, barely went through the motions of disputing infringement. The full extent of Mr. Anderson's permitted testimony relevant to the single disputed issue on infringement—namely, whether the front rib is a "formation arranged to reduce canister rocking"—was as follows:

> Q. Mr. Anderson, did you hear Dr. Lewis testify yesterday and today regarding the '289 patent?
>
> A. I did, yes.
>
> Q. And hearing that testimony, did you -- were you able to determine whether or not Dr. Lewis demonstrated that the rib he identifies as the inner wall canister support formation does anything to *prevent* rocking?
>
> A. No.

FOF 73-74; Tr. 479:14-21. Based on that single word response—and on that basis ***alone***—Mr. Anderson proceeded to testify that Cipla's device does not have an inner wall canister support formation lying in the common plane, and therefore does not infringe. *Id.* at 479:22-480:18.

As a threshold matter, Mr. Anderson's perfunctory testimony did not even address the salient issue. The parties agreed-upon construction for "canister support formation" was "a formation arranged to *reduce* canister rocking," not one (per Mr.

Anderson's testimony) to "***prevent***" rocking.[5] FOF 75; D.E. 102, at 4. It was undisputed at trial that there is "very much" a difference between ***reducing*** rocking and ***preventing*** rocking; yet for infringement of Claim 1, the rib need only be arranged to reduce rocking, not altogether prevent it. FOF 76-77; Tr. 407:1-22. Mr. Anderson's testimony applying the wrong construction is irrelevant as a matter of law. *See, e.g.*, *Cordis Corp. v. Boston Sci. Corp.*, 658 F.3d 1347, 1357 (Fed. Cir. 2011) (a court "must disregard the testimony of [an] expert . . . [if] based on an incorrect understanding of the claim construction"); *see also* FOF 78.

But even setting aside that threshold, fatal flaw, Mr. Anderson's only admitted testimony is too conclusory to be meaningful. Mr. Anderson fails even to offer his *own* opinion as to whether or not the front rib is arranged to prevent—let alone reduce—rocking. Tr. 479:14-21. Instead, Mr. Anderson offered only his unexplained opinion that Dr. Lewis's analysis was insufficient, without offering a scrap of explanation for why. *Id.* Certainly, he offered no testimony to bolster Cipla's theory—argued in Opening, but supported nowhere else—that the mounting tabs prevent the canister from contacting the front rib. *Id.* In short, Mr. Anderson offered no response to Dr. Lewis's thorough explanation or demonstration (in multiple experiments) that the canister touches the front wall and rocks more without the front rib in place or any

[5] Cipla sought to introduce equally conclusory testimony under the correct construction, Tr. 469:10-13, but the Court properly precluded this testimony given Mr. Anderson's failure to apply that construction in his report, Tr. 469:14-479:12.

testing of his own. A bare assertion of noninfringement cannot overcome the evidence and data Teva and Dr. Lewis offered. *Intell. Sci. & Tech., Inc. v. Sony Elecs., Inc.*, 589 F.3d 1179, 1184 (Fed. Cir. 2009) ("An expert's unsupported conclusion on the ultimate issue of infringement will not alone create a genuine issue of material fact."); *Warner-Lambert*, 418 F.3d at 1341-42 ("[B]ald assertion" of noninfringement insufficient absent "specific evidence"); *Arthur A. Collins, Inc. v. N. Telecom Ltd.*, 216 F.3d 1042, 1046 (Fed. Cir. 2000).

2) Mr. Anderson Directly Contradicted His Sworn Deposition Testimony.

Even had Mr. Anderson applied the correct construction (he did not) or offered more than conclusory testimony in support of his incorrect construction (he did not), his testimony that the front rib in question is somehow not an "inner wall canister support formation" would not have been credible. The reason is simple: he repeatedly testified to the opposite at his deposition. FOF 79-83. As cross examination revealed, Mr. Anderson testified *four* separate times under oath that the front rib—located between the two mounting tabs—*is* an inner wall canister support formation, FOF 80:

- "Q. In between the two mounting tabs is a small inner wall canister support formation, right?" A. Yes." *See* Tr. 513:22-514:14 (discussing "transcript snap number 6," attached hereto as Ex. A (87:12-14)); FOF 80.
- "Q. Sorry, you agree that there are seven inner wall canister support formations in defendants' ANDA products that do not lie in a common plane with the center of the central outlet port and castellation [actuation member],

right? A. Well wait a minute. There is one that is in the common plane, yes, that has been marked with a yellow dot." *See* Tr. 508:18-509:19 (discussing "Transcript Snap No. 4," attached hereto as Ex. B (137:18-23), referencing image at FOF 81).

- "Q. . . . There is one inner wall canister support formation, that is the one between the two mounting tabs, right? A. Yes." *See* Tr. 510:7-511:2 (playing "Video Clip A", transcript attached hereto as Ex. C (137:24-138:2)); FOF 82.
- "Q. So the inner wall canister support formation in between the two mounting tabs of defendants' ANDA product does lie in a common plane with a castellation [*i.e.*, actuation member] and the center of the central outlet port as shown by the red line, right? A. Yes." *See* Tr. 511:12-13 (playing "Video Clip B", transcript attached hereto as Ex. D at 138:3-8); FOF 83.

Cipla's sole non-infringement argument depends on a contrary conclusion.

3) Mr. Anderson's Narrative Regarding the Purpose of the Front Rib Is Irrelevant.

The remainder of Mr. Anderson's testimony regarding the front rib is simply irrelevant. When asked about "the purpose of the rib at the front of Cipla's ANDA product," Mr. Anderson testified for nearly two pages. Tr. 482:15-484:11. Charitably interpreted, Mr. Anderson believes that the front rib serves a purpose apart from reducing rocking—that it creates "interference fit" with an "upstand" on the dose counter to help the dose counter stay in the inhaler body. *Id.* That is wholly beside the

point: Mr. Anderson never testified that performing the "interference fit" function somehow precludes the rib from also reducing rocking. FOF 85. Indeed, that cannot be the case. As Dr. Lewis explained, the dose counter contains multiple "upstands" or "notches," several of which mate with ribs *other* than the front rib, Tr. 408:5-15; PTX-372, which other ribs Cipla agrees are "inner wall canister support formations," FOF 85. Accordingly, there is nothing about performing an "interference fit" function that somehow precludes a rib from reducing rocking, and thus infringing Claim 1 of the '289 Patent. FOF 85. [redacted]

Cipla likewise cannot avoid infringement by giving the front rib a brand-new name. Cipla and Mr. Anderson called the front rib a "dose counter connecting rib" (rather than "inner wall canister support formation"), Tr. 48:5-7, 48:11-15, 48:18-20, 57:6 (Cipla opening statement), which cross examination revealed to be a neologism conjured for this trial, FOF 84; Tr. 256:6-11 (Dr. Lewis confirming he never heard the term "dose counter connecting rib" in his thirty years' experience with inhalers). Of course, a rib's label is irrelevant—the question is whether the rib is arranged to reduce canister rocking. Tr. 256:12-14 (Lewis). Since other dose counter "notches" connect to ribs Cipla concedes are inner wall canister support formations, even Cipla accepts

that a "dose counter connecting rib" can also be an "inner wall canister support formation." FOF 85.

Regardless, Mr. Anderson's testimony about the front rib's purpose does not address the legally salient question—namely, whether it is, ***in fact***, arranged to reduce rocking. A rib may reduce rocking—and thus be an "inner wall canister support formation" according to the parties' agreed-upon construction—even if it were included in the inhaler body for a different purpose. FOF 85. "Direct infringement is a strict-liability offense." *Commil USA, LLC v. Cisco Sys., Inc.*, 575 U.S. 632, 639 (2015) ("[A] defendant's mental state is irrelevant."). Whatever its primary purpose, the front rib is "arranged to reduce canister rocking" and is thus an "inner wall canister support formation" within the meaning of claim 1. *See* D.E. 217 (Markman Op.) at 5-6; *Toshiba Corp. v. Imation Corp.*, 681 F.3d 1358, 1368-69 (Fed. Cir. 2012) (rejecting non-infringement argument that element did not infringe because it did not have the "purpose" of performing the claim limitation).

d. Cipla's Efforts to Criticize Dr. Lewis's Testimony Fail.

As described above, Cipla failed to dispute infringement through its own expert. Offering no experiments or analysis of its own, Cipla resorted to taking pot-shots at Dr. Lewis's well-supported opinion and the experiments underlying it. None of Cipla's half-baked theories are supported by the evidence, and Teva easily showed it is "more likely than not" that the front rib is "arranged to reduce canister rocking."

1) The "Mounting Tabs" Are Irrelevant.

In its opening statement, Cipla promised to show that it was "***impossible***" for the canister to contact the disputed rib because the canister could not "get past" the two "mounting" tabs in the corners of the inhaler body. Tr. 57:7-11. Cipla adduced no evidence to support this claim at trial. Mr. Anderson, said nothing about mounting tabs in his infringement analysis. FOF 87; Tr. 479:14-21, 482:15-484:11. Nor could he, having conducted precisely zero experiments to support Cipla's claim. *Id.*; Tr. 519:8-521:8. Again, this is not surprising—the experiments would have shown what any unbiased examination of Cipla's device demonstrates—*i.e.*, that the canister in the device *does* contact the front rib, and that Cipla's only defense to infringement thus fails.

Nothing else supports Cipla's claim either. Certainly, Dr. Lewis's testimony does not. Dr. Lewis repeatedly explained that he did not remove the mounting tabs in his experiments because they were necessary to hold the dose counter in place and because they "did not interfere" with his testing. FOF 88; Tr. 223:19-224:1; 229:13-25. On cross examination, Dr. Lewis expressly rejected Cipla's theory, reiterating that the canister contacts the front rib even when the mounting tabs are present:

> Q. Dr. Lewis, I want to make sure I have your testimony right. You're saying when I put a canister in the inhaler body, it hits that little front rib and not the mounting tabs that extend more than ten times further into the inhaler canister space, that free space in the inhaler body? That's your testimony. Right?
>
> A. Yes.

Tr. 374:22-375:5; FOF 89. Indeed, Dr. Lewis explained that the mounting tabs "are deliberately put ***out of the way*** of inhalation, the mouthpiece, ***as well as the canister*** and the airways." Tr. 366:10-367:4 (emphasis added); FOF 88.

Accordingly, there is zero record evidence for Cipla's bald assertion that the mounting tabs prevent the canister from contacting the front rib. While Cipla's attorney argument needs no rebuttal, Teva adduced ample contrary evidence. *Warner-Lambert*, 418 F.3d at 1341-42 ("[B]ald assertion" of noninfringement insufficient absent "specific evidence"); FOF 88-89; PTX-178 (when front rib is removed, the canister can slide down the front wall of the inhaler even though the mounting tabs are still present). Dr. Lewis's testimony and experiments[6] demonstrate that Cipla is wrong. Cipla offered no testimony—let alone data—to rebut them.

2) Cipla's Objections Were Baseless and Cannot Avoid a Finding of Infringement

Instead of performing experiments, or offering any expert explanation of non-infringement, Cipla staked its case on baseless objections to Dr. Lewis's testimony. Dr. Lewis's testimony was supported by his reports and elicited directly by Cipla's counsel on cross in any event. Regardless, with or without the testimony to which Cipla objected, the preponderance of the evidence firmly supported infringement.

[6] The fact that Dr. Lewis did not remove the mounting tabs, Tr. 375:6-18, is plainly irrelevant to Cipla's (unsupported) assertion that when the mounting tabs are ***present*** they prevent the canister from contacting the front rib.

a) Cipla's Objections Were Baseless.[7]

Dr. Lewis's testimony was entirely supported by his reports.

Incredibly, Cipla first objected when Dr. Lewis testified that if the canister in Cipla's Products is rocked forward, it contacts the front rib. Tr. 213:18. Cipla's counsel insisted that eyesight alone was insufficient to observe this basic fact, and that Dr. Lewis "would need to do a test" and "some kind of cut away" that his report did not include. Tr. 216:10-12. Nothing could be further from the truth. Dr. Lewis explained in his report that he "disagree[d with Mr. Anderson] that any analysis would be necessary to establish that the rib closest to the mouthpiece of the device limits rocking—by extending into the cavity of the inhaler, it necessarily limits the canister's freedom of movement in the direction of the front of the device." Ex. E (Reply Rept.) ¶ 61. At trial, Dr. Lewis did no more than illustrate this very same, fully-disclosed opinion: He held up Cipla's product, moved the canister towards the front of the device, and demonstrated that the canister's freedom of movement was restricted by its contact with the rib. Tr. 213:12-16 ("Well, you can tell by simply looking. When you hold the inhaler, you can just push it [the canister] and you can see it touches [the rib] before it touches the inner wall.").

It is unclear what daylight Cipla sees between Dr. Lewis's expert report and his

[7] The Court indicated it would take supplemental submissions on this issue. Tr. 217:12-15. There is no basis to exclude Dr. Lewis's testimony, as the Court ruled at trial, Tr. 217:5-11, nor is it clear to which lines of testimony Cipla's objections would apply. Should Cipla identify such testimony in response, Teva will respond accordingly.

testimony. Indeed, the basis for Cipla's objections appeared to change over the course of Dr. Lewis's examination, much of it revolving around the professed belief of Cipla's counsel (but never any witness, *supra* Section II.A.2.d.1) that the canister touches the mounting tabs before it touches the front rib. Tr. 216:5-9. The testimony that drew this objection did not even *mention* mounting tabs—but even setting that aside, Cipla's disagreement with Dr. Lewis's properly disclosed opinion would be a basis for cross examination, not preclusion of the testimony.

Naturally, Cipla's counsel ***did*** cross examine Dr. Lewis on this opinion, where counsel expressly elicited precisely the testimony Cipla earlier sought to preclude:

> Q. Dr. Lewis, it's your opinion that by extending into the cavity of the inhaler body . . . the front rib necessarily limits the canister's freedom of movement in the direction of the front of the device. Right?
>
> A. Yes.
>
> Q. And you offered that opinion in your report. Right?
>
> A. Yes.
>
> Q. And that's only true if the front rib of the inhaler body can actually contact the canister when it rocks. Right?
>
> A. Yes.

Tr. 370:25-371:12. In short, Cipla's ***own*** questioning (1) directly called for the testimony its counsel earlier moved to strike, and (2) established that such testimony was equivalent to the explicit statement in Dr. Lewis's report. On cross examination, Dr. Lewis *also* testified that the videos he supplied of his experiments (PTX-178 and

PTX-179)—as well as his description of those experiments in his reports—demonstrate that the front rib contacts the canister and is arranged to reduce rocking. Tr. 371:21-373:13; 385:20-386:8 (explaining that description of experiments in reports shows contact with front rail). In particular, Dr. Lewis explained that when Cipla's canister is rocked towards the front of the device, but the front rib has been removed, the canister touches the front wall and then slides down the front wall when it is depressed. *Id.* This explanation comes directly from his report and the videos, *see* Ex. E (Reply Rept.) ¶ 63, and it shows that if the front rib is removed, the canister touches the wall where the rib would have been, Tr. 385:20-386:8 ("I am talking about sliding down the front face of that wall. If the formation is there, it will touch it, it will restrict movement."); Tr. 403:17-404:7, 404:16-17; *see also supra* Section II.A.2.d.1 (cross examination eliciting Dr. Lewis's opinion that canister hits front rib, not mounting tabs).

Cipla's repeated objections reflect that its only hope of avoiding infringement was to exclude evidence of the simple, observable fact that the canister contacted the front rib, and then to argue failure of proof. Patent law does not permit these antics. Dr. Lewis offered precise testimony designed to show a simple fact, all of which was well-supported by his report and elicited explicitly on cross examination in any event.

Regardless, there is no basis to take the "'extreme' sanction" of excluding Dr. Lewis's testimony under the relevant Third Circuit standard. *Meyers v. Pennypack Woods Home Ownership Ass'n*, 559 F.2d 894, 904-05 (3d Cir. 1977). All relevant *Pennypack* factors weigh in favor of admitting the evidence. *Id.* ("(1) the prejudice or surprise in fact of

the party against whom the excluded witnesses would have testified, (2) the ability of that party to cure the prejudice, (3) the extent to which waiver of the rule against calling unlisted witnesses would disrupt the orderly and efficient trial of the case or of other cases in the court, and (4) bad faith or willfulness in failing to comply with the court's order."). There can be no prejudice or surprise to Cipla as to Dr. Lewis's testimony, which was not only plainly disclosed by, but also follows directly from, Dr. Lewis's report, reflects an observable fact, and had never been challenged by Cipla until trial.[8] Indeed, Cipla was apparently sufficiently on notice of Teva's infringement theory that it came prepared with attorney argument in rebuttal regarding mounting tabs, but nonetheless chose to generate not a shred of evidence in support. That choice reflects strategy, not prejudice. No prejudice existed, and Cipla could have cured any that did. Certainly, admitting Dr. Lewis's testimony would not disrupt the orderly proceedings of the trial, as that testimony has already been adduced and Cipla—again, sufficiently aware of Teva's theory to know how it wished to respond—decided not to adduce any proof. Finally, there is simply no evidence of bad faith—Teva disclosed its theories to the best of its ability in light of Cipla's shifting arguments. The "'extreme' sanction" of excluding evidence is not appropriate here under *Pennypack*. *Id.*

[8] Mr. Anderson's report instead suggested that the Common Plane limitation required that the rib prevent rocking that would otherwise have been sufficient to cause the dose counter to record a count. Ex. G at ¶¶ 82-86. Dr. Lewis disagreed both that the Common Plane limitation contained such a requirement, and also showed that Mr. Anderson was factually incorrect.

b) Cipla's Objections Cannot Defeat Infringement

Even were all of the testimony to which Cipla objected stricken, the balance of the infringement evidence would still weigh firmly in Teva's favor. The Court made plain that "if [Dr. Lewis's] report creates some impressions or inferences as to the touching," Teva was free to argue as much and the Court could draw its own conclusions. Tr. 243:11-17. As demonstrated above, Dr. Lewis's report plainly asserts that the canister touches the front rib when rocked—but even were the Court to disagree, there is no doubt the report creates such an inference. Regardless, Dr. Lewis testified without objection that the very existence of the front rib—the fact that it "extend[s] into the cavity of the inhaler body . . . necessarily limits the canister's freedom of movement in the direction of the front of the device." Tr. 370:25-371:5. That testimony *alone* carries the day given the absence of any contrary testimony from Mr. Anderson. *Supra* Section II.A.2.c. But that testimony does not stand alone. Dr. Lewis *also* provided video evidence that removing the front rib leads to dose counter errors caused by rocking *only* in the forward direction. PTX-178; *supra* Section II.A.2.b. He further testified that when he performed the experiment shown in PTX-178, he slid the canister down the wall of the inhaler body—just as he described in his report—and the canister therefore touched the inhaler wall at a location that the front rib would have occupied, had it not been removed. Tr. 404:4-7, 404:16-17. This evidence easily outweighs the sum total of Cipla's non-existent rebuttal.

B. Cipla Infringes the '587 Patent.

As described below, independent claims 1 and 12 of the '587 Patent are nearly identical to claim 1 of the '289 Patent, except that the '587 Patent claims include an *additional* limitation relating to "unwanted actuation of the dose counter" or "dose count errors." FOF 107; JTX-003; JTX-004. Cipla disputes that it infringes the additional limitations (in addition to its argument regarding the front rib, addressed above).

1. Cipla Infringes Claim 1 of the '587 Patent.

Claim 1 of the '289 Patent and claim 1 of the '587 Patent are compared below in PDX-2-078. FOF 107. As Dr. Lewis testified, the grey language is the same in both claims, the green language is the Common Plane Limitation, and the yellow language reflects an additional limitation in claim 1 of the '587 Patent regarding "unwanted actuation of the dose counter." Tr. 263:6-264:2. By establishing infringement of claim 1 of the '289 Patent, Teva has demonstrated that Cipla's ANDA Products meet the grey and green language of claim 1 of the '289 Patent. FOF 108. To prove infringement of the claim 1 of the '587 Patent, Teva need only further show that Cipla's device meets the requirement that the "first inner wall canister support formation protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler." FOF 108; Tr. 266:14-21 (Lewis).

'289 Patent, Claim 1	'587 Patent, Claim 1
1. An inhaler for metered dose inhalation, the inhaler comprising: a main body having a canister housing, a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister, wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall, and wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port, **the inner wall canister support formation, the actuation member, and the central outlet port lying in a common plane coincident with the longitudinal axis X.**	**1** An inhaler for metered dose inhalation, the inhaler comprising: a main body having a canister housing, a medicament canister, which is moveable relative to the canister housing and retained in a central outlet port of the canister housing arranged to mate with a canister fire stem of the medicament canister, and a dose counter having an actuation member having at least a portion thereof located in the canister housing for operation by movement of the medicament canister, wherein the canister housing has an inner wall, and a first inner wall canister support formation extending inwardly from a main surface of the inner wall, wherein the canister housing has a longitudinal axis X which passes through the center of the central outlet port, and **wherein the first inner wall canister support formation, the actuation member, and the central outlet port lie in a common plane coincident with the longitudinal axis X such that the first inner wall canister support formation protects against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler.**

Here again, the evidence decisively favors Teva's position. Dr. Lewis testified unequivocally that Cipla's products meet this final (yellow) limitation, based on his experiment recorded in PTX-178, described above in Section II.A.2.b. As he explained, this video demonstrates that the front rib "protects [guards] against unwanted actuation of the dose counter by reducing rocking of the medicament canister relative to the main body of the inhaler." Tr. 267:22-270:7; FOF 110 (agreed-upon claim construction substitutes "guard" for "protect"). Dr. Lewis explained that after he seated the canister in the stem block by twisting it, he rocked the canister towards the front of the inhaler (where the front rib would have been located, had it not been removed), and observed multiple unwanted actuations of the dose counter (*i.e.*, "count not fires"), because "when the support formation is not there, it doesn't limit the movement and it causes the count and the rocking." *Id.* In short, when the front rib is removed, canister rocking causes unwanted actuation. *Id.* PTX-178 thus demonstrates that the front rib "guards against unwanted actuation of the dose counter . . . by reducing rocking of the

medicament canister relative to the main body of the inhaler." FOF 115-16.

Cipla offered two unavailing responses. The first was to present a smattering of unsubstantiated theories regarding flaws in Dr. Lewis's video—addressed above in Section II.A.2.d. The second was Mr. Anderson's testimony that math modeling shows "it is not possible to rock Cipla's canister enough to create a count." Tr. 489:9-20. Again, the entirety of Mr. Anderson's conclusory testimony comprises a few lines:

> Yeah. I had a look at the risk of looking at unwanted actuation within the dose counter on looking at reducing rocking. And I did -- well, I did a bit of math modeling just to try and understand how much rocking was going to be needed to cause a count. And based on the information that I had, I did an analysis and the summary was that Cipla ANDA product does not meet that common plane limitation or unwanted actuation of the dose counter by reducing rocking, which is, obviously, the limitation of the '587 patent, but, in summary, it is not possible to rock Cipla's canister enough to create a count. So it does not infringe Claim 1 of the unwanted actuation.

Tr. 489:9-20. Once again, Mr. Anderson failed to explain any basis whatsoever for his opinion, except for a vague reference to "a bit of math modeling" and "an analysis" before concluding that "it is not possible to rock Cipla's canister enough to create a count." No record evidence identifies or substantiates the "bit of math modeling," and it certainly cannot overcome Dr. Lewis's well-reasoned explanation backed by visual, experimental evidence. But even had Mr. Anderson offered and explained an actual mathematical model, the proof here is in the pudding. Dr. Lewis's video demonstrated that whatever "model" Mr. Anderson has in mind, it is wrong—it ***is*** possible to rock the canister enough to create an unwanted count. PTX-178; FOF 117; Tr. 272:4-14

(Lewis). And Dr. Lewis explained *why* any such model would be wrong—it would not account for the fact that the canister might be rocked ***while*** it is being depressed, which is an action consistent with patient use. Tr. 272:19-273:8 (Mr. Anderson's model "is considering pushing the canister sideways, but it's not considering pushing downwards on the canister while you are pushing sideways."). Cipla offered no experiments or data to support its request that the Court not believe its eyes and reject what Dr. Lewis plainly showed. FOF 118; Tr. 271:2-13 (Lewis). The preponderance of evidence establishes infringement of Claim 1 of the '587 Patent.

2. Cipla Infringes Claim 12 of the '587 Patent.

Claim 12 of the '587 Patent is nearly identical to claim 1 of the '587 Patent, except that its final limitation requires "that the first inner wall canister support formation protects against dose count errors by reducing rocking of the medicament canister towards or away from the actuation member." FOF 141; JTX-004. Unlike '587 Patent claim 1's requirement to protect against only "unwanted actuation" (*i.e.*, "count-not fire errors"), claim 12's reference to "dose count errors" includes ***both*** "count-not-fire" and "fire-not-count" errors, and limits the direction of rocking to rocking "towards or away from the actuation member." JTX-004; Tr. 277:13-278:3 (Lewis).

For the reasons explained above, Dr. Lewis's experiment in PTX-178 (when he rocked the canister *towards* the actuation member in a common plane with the disputed rib) established infringement of this limitation, because it showed that the front rib protects against "count-not fire" errors. *Supra* Sections II.A.2.b, II.B.1. But Dr. Lewis

performed yet another experiment, in which he demonstrated that the absence of the front rib can also lead to "fire-not-count" errors. PTX-179; Tr. 279:14-282:12 (Lewis). Dr. Lewis removed all the support ribs from Cipla's product, but left the mounting tabs in place, then rocked the canister towards the front of the inhaler (in the direction of the removed, front rib) and observed that the inhaler could expel medication ("fire") without the dose counter recording a count. *Id.* In other words, without the front rib, rocking in the direction of the actuation member (*i.e.*, in the same direction as the missing rib) can cause "fire-not-count" errors in Cipla's device. *Id.* On this basis, Dr. Lewis concluded that the front rib protects against dose count errors in the manner claim 12 requires. *Id.* at 282:18-283:1.

Yet again, Cipla offered no experiments or data in response. Instead, it relied again on Mr. Anderson's purported "bit of math modeling," which (1) was debunked by Dr. Lewis's experiment in PTX-178, as described above, and (2) was limited to "count-not-fire" scenarios, rather than the "fire-not-count" scenario depicted in PTX-179. Tr. 492:2-11. Cipla's remaining criticism miss the mark. Mr. Anderson suggested that Dr. Lewis failed to prime the device, that this failure caused the observed dose counter errors, and then testified, without a shred of evidence in support that "if it was primed, it would have . . . worked I think perfectly." Tr. 495:18-496:21. Rank speculation cannot overcome Dr. Lewis's experimental proof, and common-sense belies Mr. Anderson's speculation. Dr. Lewis's video showed three consecutive instances in which Cipla's inhaler fired but did not count. Even were one to consider

those first two fires of the canister "priming" doses, the video still reflects a third dose counter error caused by rocking. PTX-179; Tr. 405:9-13 (Lewis). Of course, as Dr. Lewis explained, the dose counter should accurately keep track of priming doses just as well as any other dose, and thus all three instances of fire-not-count errors are problematic. Tr. 391:16-392:12; 405:9-13. Again, a preponderance of evidence proves Cipla infringes claim 12 of the '289 Patent.

3. Cipla Infringes Claims 2, 4, 6, and 7 of the '587 Patent.

The dependent limitations of claims 2, 4, 6, and 7 of the '587 Patent mirror the dependent limitations of claims 2, 4, 5, and 7 of the '289 Patent. As described above, Cipla did not contest that its products meet these additional limitations, and the unrebutted evidence of infringement is provided above in Sections II.A.1.b-II.A.1.e.

C. Cipla Infringes the '808 Patent.

The evidence presented at trial also shows that Cipla infringes claim 28 of the '808 Patent. After the Court's *Markman* order rejected the vast majority of Cipla's non-infringement defenses, *see* D.E. 217, 218, Cipla and its expert, Mr. Anderson, disputed infringement of claim 28 on only two grounds. First, Cipla argued the "leaf spring" in its ANDA Products is not a "regulator" because it does not exert any force on its "counter display." Second, Cipla argued that the Dr. Lewis's testing did not establish that Cipla's leaf spring provides a resistance force of more than 0.3 N in the "opposite direction" of the counter display, which it now asserts is required for infringement. Neither argument has merit. As with Cipla's efforts to insert a "prevents rocking"

requirement into the '289 and '587 Patents, Cipla's arguments insert additional, unsupported requirements into the claims and ignore the evidence. The evidence clearly shows that Cipla infringes claim 28 of the '808 Patent.

1. Cipla's ANDA Products Satisfy Each Undisputed Limitation of the Asserted Claims of the '808 Patent.

Claim 28 Patent depends from claim 27, which, in turn, depends from claim 1:

> **1.** A dose counter for an inhaler, the dose counter having a counter display arranged to indicate dosage information, a drive system arranged to move the counter display incrementally in a first direction from a first station to a second station in response to actuation input, wherein a regulator is provided which is arranged to act upon the counter display at the first station to regulate motion of the counter display at the first station to incremental movements.
>
> **27.** The dose counter as claimed in claim **1** in which the regulator provides a resistance force of greater than 0.1 N against movement of the counter display.
>
> **28.** The dose counter as claimed in claim **27** in which the resistance force is greater than 0.3 N.

JTX-002 ('808 Patent). To infringe claim 28, a dose counter must satisfy claim 1 and further comprise a "regulator" that "provides a resistance force" of "greater than 0.3 N" "against movement of the counter display." FOF 153; PDX-2-087.

Cipla does not dispute that its ANDA Products satisfy the vast majority of these required elements. Nor could it. ***First***, Cipla has stipulated that its ANDA Products comprise "a dose counter for an inhaler." FOF 157.

Second, Cipla's units display ring is "a counter display arranged to indicate

dosage information" under the ordinary and customary meaning of that term. During claim construction, Cipla sought to avoid infringement construing the term "counter display arranged to indicate dosage information" to mean a "structure displaying the number of doses remaining." D.E. 217, at 20. Because its dose counter contains two components (the "units display ring" and a "tens cone"), Cipla sought to create an artificial distinction between dose counters that contained one counter display and those that contained multiple counter displays. The Court rejected that effort, agreeing with Teva that the term "counter display" required no construction and should be given its plain and ordinary meaning. D.E. 217, at 20-21; D.E. 218, at 3. Applying that meaning, Dr. Lewis testified that Cipla's units display ring is a "counter display" because it indicates dosage information by displaying the ones (*i.e.*, units) digit for each remaining dose. FOF 158-60.

Neither Cipla nor its expert dispute Cipla's units display ring is a counter display under that term's plain and ordinary meaning. Although Cipla's dose counter contains ***a second*** counter display (a "tens cone") that displays dosage information (a tens digit), that does not affect whether Cipla's units display ring ***itself*** is a "counter display." Whatever the tens cone indicates, the units display ring indicates dosage information; it is thus a "counter display" under the term's plain meaning. FOF 158-60.

Even were Cipla's tens cone relevant to whether the units display ring is a "counter display," Cipla's Products would still satisfy this limitation. When Cipla's Products have fewer than ten doses remaining, the units display ring indicates all

available dosage information because, at those times, the number of remaining doses consists of the single digit indicated by the units display ring. "It is well settled that an accused device that 'sometimes, but not always, embodies a claim[] nonetheless infringes.'" *Broadcom Corp. v. Emulex Corp.*, 732 F.3d 1325, 1333 (Fed. Cir. 2013) (quoting *Bell Commc'ns Res., Inc. v. Vitalink Commc'ns Corp.*, 55 F.3d 615, 622-23 (Fed. Cir. 1995)).[9] Thus, Cipla's units display ring is a "counter display" under any meaning of the term, regardless of what information Cipla's other components also provide.

Third, Cipla's lid, indexer, and units teeth ring constitute the claimed "drive system arranged to move the counter display incrementally from a first station to a section station in response to actuation input." During claim construction, Cipla argued that the "first station" and "second station" must be "structures," not "regions." The Court disagreed, adopting Teva's position that the "first station" and "second station" may be "regions" because the patent describes them as "regions." D.E. 217, at 21-23; D.E. 218, at 3. Dr. Lewis testified, without contradiction, that Cipla's lid, indexer, and units teeth ring satisfy this limitation, because during use, those components move the units display ring incrementally from a first region to a second region. FOF 161-65. Thus, the Court should find that Cipla's ANDA Products satisfy this limitation, too.

2. Cipla's Products Comprise a "Regulator" "Arranged to Act Upon the Counter Display at the First Station to Regulate

[9] *See also Core Wireless Licensing S.A.R.L. v. Apple Inc.*, 899 F.3d 1356, 1363 (Fed. Cir. 2018) ("[I]nfringement is not avoided merely because a non-infringing mode of operation is possible.") (citing *z4 Techs., Inc. v. Microsoft Corp.*, 507 F.3d 1340, 1350 (Fed. Cir. 2007); *VirnetX, Inc. v. Cisco Sys., Inc.*, 767 F.3d 1308, 1322 (Fed. Cir. 2014)).

Motion of the Counter Display to Incremental Movements."

Contrary to Cipla's contention, the evidence presented at trial established that Cipla's leaf spring is a "regulator." As the patent explains, and Dr. Lewis testified, one challenge of designing a dose counter is ensuring that the counter display moves forward in complete (rather than partial) increments—and only in complete increments. FOF 167. To overcome this challenge, the inventors introduced a "regulator," which "regulates" (or, per the parties' agreed upon claim construction, "modulates") the "motion of the counter display to incremental movements." D.E. 102, at 3; FOF 168.

Cipla's leaf spring acts on the units display ring (the claimed "counter display") to ensure that the units display ring moves in such increments. FOF 169. Specifically, when Cipla's Products are assembled, the canister sits on top of the indexer, which sits on top of the leaf spring, ***which "sits in the units display ring***." FOF 170; Tr. 291:18-293:11 (Lewis). Thus, when a patient pushes down on the canister, the canister pushes down on the indexer, which pushes down on the leaf spring, ***which pushes down on the units display ring***. FOF 170. If a patient pushes down on the canister with too little force, the leaf spring ensures that the units display ring does ***not*** move, such that the ***display*** does not record a count. FOF 171. Conversely, if the patient pushes down with enough force, the leaf spring ensures that the units display ring increments completely and displays the next digit, ***without*** "allow[ing] the dose counter to hover between two doses." FOF 172; Tr. 295:3-12 (Lewis).

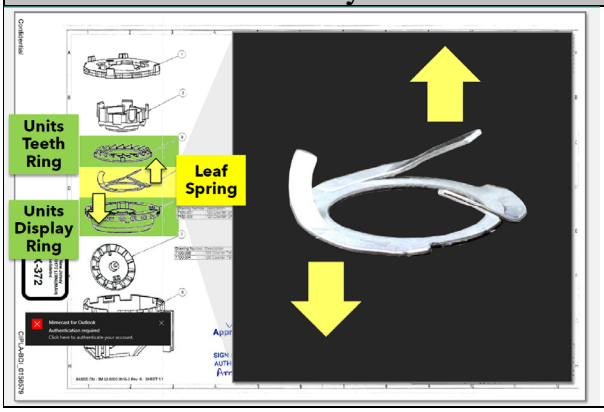
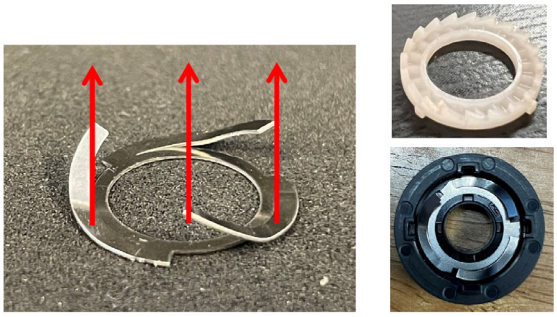
Although Cipla runs in circles to deny that its leaf spring is a "regulator," its

arguments have no basis in the claim language or physical reality. Mr. Anderson first testified that Cipla's Products have no "regulator" because "[they're] not a tape-based device. [They're] a mechanical device. And when you have a look at the plaintiff's product, it's a tape." Tr. 462:15-463:15. Second, he argued that Cipla's leaf spring is not a "regulator" because it only exerts an "upwards" force against the indexer and does not exert any downward force against the units teeth ring. Tr. 463:18-465:3.

Mr. Anderson's argument that Cipla has no "regulator" because "it's not a tape-based device" reflects a legally improper infringement inquiry. As its plain language indicates, claim 28 (and claims 1 and 27 from which it depends) have do not require that the dose counter be "tape-based." FOF 173. While other claims (such as claim 2) do recite and require tape, claims 1, 27, and 28 do not recite or require "tape" or tape-based counters. FOF 173. As with the '289 and '587 Patents, Cipla's reliance on "tape-based devices" reflects that it hopes to avoid infringement by inserting words into claims—a legally foreclosed approach. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1320 (Fed. Cir. 2005) (en banc). Mr. Anderson likewise erred by impermissibly comparing Cipla's and Teva's inhalers, rather than by comparing the former to the claims. *See Int'l Visual Corp. v. Crown Metal Mfg. Co.*, 991 F.2d 768, 772 (Fed. Cir. 1993) (per curiam).

Mr. Anderson is also wrong that Cipla's leaf spring only provides an "upwards" force against the indexer and does not exert any downwards force against the units teeth ring. As Dr. Lewis explained, and the Court observed, fundamental principles of physics—the "laws of Newton"—dictate that if the leaf spring pushes upwards, it must

also push downwards against the leaf spring with an "equal and opposite force." FOF 174; Tr. 291:18-293:11, 294:19-295:22; PTX-411 (Cipla ANDA Product Sample); PTX-181 (Video). In other words, "every action must have an equal and opposite reaction." FOF 174; Tr. 291:18-292:2. Mr. Anderson could not—and did not—address this fundamental, immutable rule of physics, which refutes his argument.

Dr. Lewis's Testimony	Mr. Anderson's Testimony
	

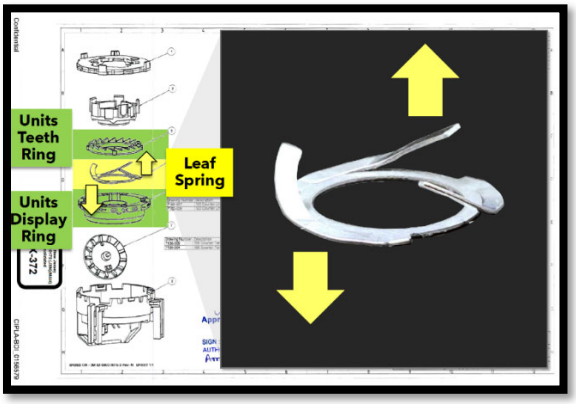
Compare Tr. 291:5-292:15 *and* PDX-2-098 (Lewis), *with* Tr. 463:18-465:3 *and* DDX2.25.

Mr. Anderson's efforts to deny the obvious aside, Aurobindo's corporate representative readily conceded that in Aurobindo's device—which Mr. Anderson agrees is the same as Cipla's—the leaf spring is a "regulator." *See infra* Section IV. Dr. Jay Holt, Aurobindo's Senior Vice President of Inhalation Research & Development, who is responsible for choosing Aurobindo's canisters and inhalers, testified that the leaf spring "help[ed] the units display ring move incrementally." FOF 204. Notwithstanding Cipla's efforts to exclude that testimony, D.E. 228; *infra* Section IV, Dr. Holt's admissions could not have been clearer, and his testimony mirrored Aurobindo's FDA submissions stating that the leaf spring was "designed to provide

unidirectional rotational force"—that it, like the claimed "regulator," was designed to ensure that the counter display moves forwards in one direction only. FOF 205.

3. Cipla's ANDA Products Comprise a "Regulator" That "Provides a Resistance Force" of "Greater than 0.3 N" "Against Movement of the Counter Display."

The evidence also establishes that Cipla's leaf spring provides a resistance force of greater than 0.3 N against movement of the units display ring. Only Dr. Lewis gathered any experimental evidence regarding the amount of force exerted by the leaf spring. As explained above, Dr. Lewis testified that the leaf spring exerts an "equal and opposite" force in both directions. FOF 174; Tr. 291:18-292:2. Thus, as a matter of simple Newtonian physics, measuring the upwards resistance force that the leaf spring exerts against the canister "directly" measures the downward resistance force that the leaf spring exerts against the counter display. FOF 184; Tr. 410:13-22.



PDX-2-098 (citing PTX-411 (Cipla Product); PTX-372 (Cipla Design Drawing)). Dr. Lewis applied this principle to measure the upwards force that the leaf spring exerts as greater than 0.3 N. FOF 183. From this, he concluded that the leaf spring exerts a

downwards force of greater than 0.3 N, which establishes infringement. FOF 182-83.

Mr. Anderson performed no testing whatsoever. Instead, he asserted that Dr. Lewis's testing did not establish infringement because it measured the resistance force exerted by the leaf spring against the counter display based on the force exerted on the canister, rather than conducting, according to Mr. Anderson, a proper direct measurement. Tr. 465:4-466:20. In so concluding, however, Mr. Anderson ignored entirely Dr. Lewis's testimony regarding the relationships between the canister, leaf spring, and units display ring. As explained above, Dr. Lewis did "directly" measure the force that the leaf spring exerts on the units display ring, ***because the upwards and downwards forces that the leaf spring exerts are the same***. FOF 184.

Regardless, there is nothing improper about proving infringement via ***indirect*** measurements; rather, a "patentee may prove infringement by 'any method of analysis that is probative of the fact of infringement,'" including "circumstantial evidence." *Martek Bioscis. Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1372 (Fed. Cir. 2009). Such evidence is especially probative here, where the expert testimony in question involves the application of "scientific fact." *Id.* Dr. Lewis was the only expert to offer a scientifically cogent explanation regarding the relevant forces. *See* FOF 174, 183-85. Mr. Anderson offered no basis to find that the force that the leaf spring exerts upwards could or would differ from the force it exerts downwards against the counter display; he conducted no experiments, collected no data on any of the forces in question, and submitted no evidence on the question. FOF 185. Nor did any other Cipla witness.

In a last-ditch effort to avoid a finding of infringement, Cipla's ***counsel*** sought to twist Dr. Lewis's statement in his report that Cipla's leaf spring "applies a resistance force opposite to the direction of the motion of the counter display" to suggest that his testing was erroneous because he did not measure whether Cipla's leaf spring exerts a "***counterclockwise***" force in the "***opposite***" direction of the clockwise-moving counter display. *See* Tr. 312:23-323:10. Cipla's attorney argument misinterprets both the claim language and Dr. Lewis's opinions.

Claim 28 does not require the regulator to provide a resistance force in the "opposite direction" of the counter display; rather, it requires that the "regulator" provide a "resistance force" "***against*** movement of the counter display." FOF 186; JTX-002 ('808 Patent (emphasis added)); Tr. 408:19-410:7 (Lewis). The fact that Cipla's leaf spring provides a ***downwards*** "resistance force" "against movement" of the units display ring, as opposed to a ***counterclockwise*** one, does not make it any less a resistance force. FOF 186-87; Tr. 315:2-24, 410:8-22 (Lewis). This is presumably why neither Mr. Anderson nor any witness endorsed Cipla's counsel's theory that Dr. Lewis should have measured the "counterclockwise force" on the counter display. Indeed, Mr. Anderson never once used the phrases "clockwise" or "counterclockwise" in his testimony, FOF 189; and arguments of counsel are not evidence of noninfringement.

Dr. Lewis's opinions are consistent with the principle that a "resistance force" need not be in a direction directly "opposite" a movement in order to work "against" such movement. Despite Cipla's efforts to confuse the issue, Dr. Lewis did not suggest

that the "regulator" must apply a force ***directly opposite*** the "counter display." Rather, he opined that that Cipla's leaf spring "provides a resistance force ***opposite to the direction*** of the movement of the counter display"—in other words, the leaf spring provides a resistance that opposes the movement of the counter display. Tr. 313:10-17. Consistent with that opinion, he testified that the regulator provides a resistance force "against movement of the counter display." FOF 181-84; Tr. 408:19-410:22. That is all the claim language requires, and establishes infringement. FOF 186-187.

Sound scientific principles support this distinction. To take a commonplace example explained by Dr. Lewis, if a person pushes their "foot down" on a merry-go-round (or "child's roundabout"), "the roundabout will stop. Without [that] foot pushing down and without any friction, the roundabout will continue." FOF 188; Tr. 315:2-24. Even though the downward force of the rider's foot is not directly "opposite" the rotation of the roundabout, it still resists its movement. *Id.* The same principle applies to many familiar situations, from record players, Tr. 410:8-22, to car brakes, in which a downward force resist movement of a rotating object, FOF 188. In the same way, Cipla's leaf spring exerts a resistance force against the rotational movement of the units display ring by applying a downward force against it. FOF 188.

Cipla's arguments are baseless, and the Court should find infringement.

III. Objective Evidence of Praise Supports Nonobviousness.

In *Graham v. John Deere Co.*, 383 U.S. 1, 17, 35-36 (1966), the Supreme Court recognized that certain objective facts can serve as indicia of nonobviousness and

"guard slipping into the use of hindsight." *Apple Inc. v. Samsung Elecs., Co.*, 839 F.3d 1034, 1052 (Fed. Cir. 2016) (en banc). Such objective indicia "may often be the most probative and cogent evidence in the record" and "establish that an invention appearing to have been obvious in light of the prior art was not." *Id.* (quoting *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538-39 (Fed. Cir. 1983)).

While objective indicia of nonobviousness "must be considered in every case where present," *id.* at 1049, the existence of objective indicia is "***not*** a requirement for patentability," and their absence is a "neutral factor." *Custom Assocs., Inc. v. Jeffrey Allan Indus., Inc.*, 807 F.2d 955, 960 (Fed. Cir. 1986) (emphasis added). Thus, a court need not resolve issues related to objective indicia if the defendant fails to carry its burden on the other elements of obviousness. *Id.*[10] Accordingly, courts uphold patents even where the patentee adduces no evidence of objective indicia whatsoever. *See, e.g.*, *MobileMedia Ideas LLC v. Apple Inc.*, 780 F.3d 1159, 1165 (Fed. Cir. 2015).

Here, Plaintiffs' evidence that Qvar® and ProAir® with dose counter have received praise from healthcare providers and patients alike compels a conclusion of nonobviousness. Industry participants are "not likely to praise an obvious advance over the known art." *Apple*, 839 F.3d at 1052. Thus, praise "provides probative and cogent

[10] *See Otsuka Pharm. Co. v. Sandoz, Inc.*, 678 F.3d 1280, 1296 (Fed. Cir. 2012) ("Because we agree . . . that the Defendants failed to prove that claim 12 of the '528 patent would have been prima facie obvious . . . , we need not address the court's findings regarding objective evidence of nonobviousness."); *Pfizer Inc. v. Teva Pharm. USA, Inc.*, 555 F. App'x 961, 971 (Fed. Cir. 2014) (similar).

evidence that [a POSA] would not have reasonably expected" the claimed invention. *Institut Pasteur v. Focarino*, 738 F.3d 1337, 1347 (Fed. Cir. 2013).

Teva's clinical expert, Dr. Reynold Panettieri—who has more than thirty years of experience in treating pulmonary disorders and has prescribed inhalers to thousands of patients during that period, FOF 191—testified that ProAir® and Qvar® with dose counter have received extensive praise in the medical industry. FOF 190, 192. As Dr. Panettieri explained, he and other physicians "pretty uniformly" describe ProAir® and Qvar® as "really state of the art" and "best in class inhalers that have dose counters" because of their accuracy, reliability, robustness, and ergonomics. FOF 192; Tr. 805:1-807:17. He further noted that his opinions were corroborated by studies finding that ProAir® with dose counter "functioned accurately and reliably in the clinical setting" and "significantly reduced" hospitalizations and emergency room visits. FOF 193; Tr: 807:18-811:9; PTX-121 (Given 2012); PTX-120 (Chipps 2017).

[redacted]

Mr. Anderson—who is not a physician and who "is not legally allowed to treat patients"—offered only one criticism of Dr. Panettieri's opinions. Tr. 814:17-816:19;

817:4-818:7. Without citing any basis in medical science, Mr. Anderson asserted that Dr. Panettieri's cited studies were not probative because they compared ProAir® with dose counter to ProAir® without a dose counter. Tr. 814:17-816:19. Even if credited, that assertion fails to address Dr. Panettieri's testimony, based on his direct interactions with other healthcare providers, that Qvar® and ProAir® have been praised as "best in class" among inhalers with dose counters. FOF 192; Tr. 805:1-807:17.

Perhaps recognizing Mr. Anderson's inability to challenge Dr. Panettieri's opinions, Cipla suggested that Teva failed to prove Qvar® and ProAir® embody the its inventions because, although Dr. Lewis "exhaustively" explained why Cipla's ANDA Products infringed the Asserted Patents, he did not address ProAir® and Qvar® with the same level of detail. Tr. 731:8-733:1. Cipla's attorney argument misses the mark. For objective indicia to have "substantial weight," a patentee need only prove that it has "a 'nexus' to the claims, *i.e.*, that there is 'a legally and factually sufficient connection' between the evidence and the merits of the patented invention." *Henny Penny Corp. v. Frymaster LLC*, 938 F.3d 1324, 1332 (Fed. Cir. 2019) (citation omitted). Teva more than satisfied that burden. Dr. Lewis testified, without contradiction, that Teva's regulatory filings (PTX-201 and PTX-212), prove Qvar® and ProAir® "meet all asserted claims." FOF 195; Tr. 728:17-729:11. Teva's inventors, Mr. Declan Walsh and Mr. Jeffrey Karg, further testified that Qvar®'s and ProAir®'s inclusion of (1) an inner wall canister support formation in a "common plane" with the actuation member and center of the central outlet port and (2) a "regulator" contributed to advantages that Dr. Panettieri

discussed. FOF 196-197; Tr. 76:25-80:12, 84:9-86:18 (Walsh); 633:1-634:17, 635:12-636:24 (Karg). Cipla's attorney argument cannot overcome that proof. FOF 195-197.[11]

IV. The Court Should Admit the Aurobindo Evidence (D.E. 234).

Cipla's infringement of the Asserted Claims is further confirmed by its extraordinary efforts to exclude the admissions of its co-defendant, Aurobindo, proffered at trial. D.E. 234. Contrary to Cipla's contention, Cipla had full notice of the taking of that evidence, and the evidence is plainly relevant because the companies' products are identical. FOF 209-21. Cipla had every opportunity to address the evidence had it wanted. To wit, Cipla could have attended the Aurobindo depositions (all available on Zoom), but chose not to do so. Thereafter, Dr. Lewis cited the evidence in his reports, and Cipla's (and Aurobindo's) expert, Mr. Anderson, admitted at trial that he had access to the testimony. FOF 221; Tr. 818:21-822:17. Cipla's refusal to engage with the evidence does not make it inadmissible. The Court should admit it.

First, Cipla's relevance objection fools no one. D.E. 228, at 1-2. Dr. Lewis testified, without contradiction by Mr. Anderson or any other witness, that there were no "meaningful differences between Cipla's [ANDA Product], whether the product

[11] Cipla's attorneys have also previously argued that Teva's evidence of objective indicia was insufficient because Qvar® and ProAir® are covered by ***other*** patents. At trial, however, Mr. Anderson offered no testimony that the inventions covered by those patents are in any way related to the praise that Dr. Panettieri discussed. *See* FOF 195-197; Tr. 814:7-816:20. Thus, Teva's testimony regarding the relationship between the claimed inventions and that praise stands unrebutted.

samples or documents, and Aurobindo['s] [ANDA Product]." *See* Tr. 138:9-141:2. The only evidence of record confirms this. [redacted]

[redacted]

[redacted]

FOF 212 (Full-Size Images); PTX-372 (Cipla Design Drawing); D.E. 234-5, [redacted]

[redacted]

Cipla's desire to oppose admission is no mystery. Aurobindo's two witnesses

[redacted]

were Dr. Jay Holt, Aurobindo's Senior Vice President, Inhalation Research & Development, who is "responsible for choosing actuators [*i.e.*, inhaler bodies] and dose counters to use in Aurobindo's inhalers"; and Deborah Carr, an Associate Director in Aurobindo's Inhalation Division who worked on Aurobindo's ANDA Products. FOF 198-199. Both witnesses had personal knowledge of Aurobindo's ANDA Products, FOF 200; and both directly contradicted Cipla's defenses at trial:

- Cipla contends it does not infringe the '808 Patent because (supposedly) its leaf spring is not a "regulator." According to Cipla, the leaf spring only acts upwards, not downwards against the counter display. *See supra* Section II.C.2. But Dr. Holt testified Aurobindo's leaf "spring also help[s] the units display ring move incrementally." FOF 205-06, D.E. 234-1, at 82:4-6.
- Cipla also contends it does not infringe the '808 Patent based on a false dichotomy between "tape-based" and "gear-based" dose counters. *See* Tr. 40:14-52:9 (Cipla's Counsel); Tr. 462:15-463:15 (Anderson); *supra* Section II.C.2. Dr. Holt's testimony belies that distinction. He testified that Aurobindo chose its dose counter because that dose counter was the "most similar" one to Qvar®, and that any differences between Aurobindo's and Teva's dose counters were "very minor." FOF 206.
- Cipla contends that Teva's inventions would have been obvious. Ms. Carr's testimony supports the opposite conclusion. [redacted]

[redacted]

Second, although Cipla argues that admission of the submitted evidence would be "extraordinarily prejudicial" because "Teva did not send any Rule 30(b)(6) deposition notice of Aurobindo to Cipla" and "did not produce the transcript of either deposition or the related documents to Cipla during discovery," D.E. 228, at 2, Cipla in fact received the deposition notices for both witnesses. FOF 216. Cipla then joined a joint filing in which Aurobindo "agree[d] to designate at least one Rule 30(b)(6) representative and to make available two Rule 30(b)(1) deponents (Jay Holt and Deborah Carr)." FOF 217; D.E. 131, at 1. As the Court noted, Cipla and Aurobindo were parties to a joint defense agreement, FOF 219; Tr. 423:14-16, and shared Mr. Anderson as an expert witness. Mr. Anderson agreed that he had access to Aurobindo's transcripts (and in fact reviewed Ms. Carr's transcript). FOF 218; Tr. 818:21-822:17.[13]

Third, Dr. Holt's deposition testimony is not "improper expert testimony by a

[13] *Otsuka Pharms. Co. v. Sandoz, Inc.*, 2010 WL 4809321, No. 07-1000-MLC (D.N.J. Jul. 26, 2010), which Cipla cited in its letter, does not advance its position. In that case, the court preliminarily agreed with several defendants (including Teva) and entered an order prohibiting the plaintiff from using deposition testimony and documents relating to certain stayed defendants. The court did not explain the basis for its ruling and expressly granted the plaintiff leave "to make further applications with respect to such evidence." *Id.* at *1. That preliminarily ruling, on a different record, says nothing about the admissibility question here.

lay witness" under Rules 701 and 702 merely because he addressed "how Aurobindo's [and Cipla's] device functions." D.E. 131, at 2. Under Third Circuit law, "a lay witness' opinion on technical matters may be admissible if it 'derive[s] from a sufficiently qualified source as to be reliable and hence helpful to the [finder of fact].'" *Forest Labs., Inc. v. Ivax Pharms., Inc.*, 237 F.R.D. 106, 114-15 (D. Del. 2006) (quoting *Asplundh Mfg. Div. v. Benton Harbor Eng'g,* 57 F.3d 1190, 1201 (3d Cir. 1995)). Dr. Holt testified as to his personal knowledge of Aurobindo's ANDA Products, not opinions formed for this litigation. FOF 200. Courts in patent cases routinely permit fact witnesses to testify about similar matters. *See, e.g.*, *Braun Corp. v. Maxon Lift Corp.*, 282 F. Supp. 2d 931, 934 (N.D. Ind. 2003), *aff'd*, 97 F. App'x 335 (Fed. Cir. 2004).[14] And indeed, Cipla itself proffered testimony from its own employee fact witness at trial as to the functioning of Cipla's device. *See* FOF 222; Tr. 538:4-10 (Rote). Cipla cannot exclude employee testimony as purported "expert opinions" only when it suits Cipla.

V. Conclusion

Thus, Teva respectfully requests that the Court find that Cipla's ANDA Products infringe each Asserted Claim of the '289, '587, and '808 Patents; find that objective evidence of praise supports the nonobviousness of the Asserted Claims; and admit Teva's proffer of Aurobindo deposition testimony and documents.

[14] *See, e.g.*, *Hynix Semiconductor Inc. v. Rambus Inc.*, No. 00-20905 RMW, 2009 WL 230039, at *10 (N.D. Cal. Jan. 27, 2009) ("[T]he court does not believe it is 'expert' testimony . . . for an engineer to describe the products he has built, or for a scientist to explain what he knew at a certain point in time.").

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Respectfully submitted,

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